

DISTRICT OF COLUMBIA
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DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
Petitioner,

v.

SIERRA INTERNATIONAL
PHARMACEUTICAL COMPANY
Respondent

Case No.: I-00-30022

FINAL ORDER

I. Introduction

By Notice of Infraction served on June 29, 2000, the Government charged Respondent Sierra International Pharmaceutical Company with violating D.C. Code § 2-2013(a), which prohibits selling or dispensing certain drugs after the expiration date on the label. The Notice of Infraction asserted that the violation occurred on June 21, 2000, and sought a penalty of \$500.00.

Respondent did not answer the Notice of Infraction within the required twenty days after service (fifteen days plus five additional days for service by mail pursuant to D.C. Code § 6-2715). Accordingly, on July 25, 2000, this administrative court issued an order finding Respondent in default and assessing the statutory penalty of \$500.00 pursuant to D.C. Code § 6-2704(a)(2)(A). Respondent filed an untimely plea of Deny on August 7, 2000, and a hearing originally was scheduled for August 31, 2000. The hearing order noted that Respondent had not

submitted any explanation for its failure to file a timely response to the Notice of Infraction, and offered Respondent an opportunity to supplement the record on that issue at the hearing.

The hearing date was later continued to October 6, 2000. Marcia Wooden, the inspector who issued the Notice of Infraction, appeared on behalf of the Government on that date. Respondent's president, Sahr Bockai, appeared on Respondent's behalf. At the conclusion of Ms. Wooden's testimony, Respondent moved to change its plea to Admit with Explanation. The Government did not object, and I accepted Respondent's plea after ascertaining that it was knowing and voluntary.

II. Summary of the Evidence

Ms. Wooten testified that she conducted an annual licensing inspection at Respondent's drug store, located at 3316 14th Street, N.W., on June 21, 2000. She discovered that Respondent had 17 different bottles of prescription medicines available on the shelves or in a refrigerator in the pharmacy department even though the expiration dates on those bottles had passed. The medicines and their expiration dates are listed on Petitioner's Exhibit 100.¹ Ms. Wooden testified that each of the medications on the list was subject to deterioration if kept beyond its expiration date.

¹ Petitioner's Exhibit 100 lists 13 different medications, along with their expiration dates. As indicated on the Exhibit, Ms. Wooden found five bottles of one medication whose expiration date had passed.

Mr. Bockai testified that he instructs his technicians to survey the stock of prescription medicines twice a year, in July and December. The technicians were supposed to mark the label of each container that was nearing its expiration date with a red "X" that would alert a pharmacist to check for the expiration date before dispensing any of the medication and to remove the container from the shelves once the expiration date had passed. He conceded that four of the medications listed on Petitioner's Exhibit 100, which were stored in the refrigerator, probably were not surveyed or marked. He had no personal knowledge that the remaining containers in fact were marked, but based his testimony on the usual practice in his store.

If the technicians found a container whose expiration date had passed, they were supposed to remove it from the shelf. Twelve of the containers listed by Ms. Wooden had expiration dates before December 1999, which would have been the date of the last technicians' survey prior to Ms. Wooden's inspection. Mr. Bockai had no explanation for why those containers remained on the shelf or in the refrigerator. He testified that he has improved his survey procedures and that he now will take an active role in making sure that expired drugs do not remain on the shelves or in the refrigerator.

Ms. Wooden did not recall seeing an "X" on any of the bottles, but testified that she was not certain whether such a mark was there.

III. Findings of Fact

1. By its plea of Admit with Explanation, Respondent has admitted violating D.C. Code § 2-2013(a).
2. On June 21, 2000, the expiration dates for at least 17 bottles of prescription drugs subject to deterioration that were available for sale in Respondent's store had passed.
3. Respondent's procedures for keeping track of the expiration dates of the drugs in its inventory were inadequate. There was no regular survey of drugs in the refrigerator, and the survey of drugs on the shelves did not result in the removal of drugs that already had expired. Respondent's president, who is a licensed pharmacist, undertook no effort to verify that his technicians performed the surveys properly. The result of these inadequate procedures was that twelve of the bottles were more than six months beyond their expiration dates, nine of them were more than a year beyond their expiration dates, and one was twenty months beyond its expiration date.
4. Respondent has accepted responsibility for the violation, and has instituted procedures to prevent further violations.
5. Respondent offered no explanation for its failure to file a timely answer to the Notice of Infraction.

IV. Conclusions of Law

1. Respondent's plea establishes that it violated D.C. Code § 2-2013(a), which governs drugs that may deteriorate and prohibits the sale or dispensing of such drugs after their expiration date.
2. Respondent's violation is aggravated by its failure to detect the expired drugs for a considerable period of time. For the majority of the expired drugs, at least two semi-annual surveys did not result in their removal from the shelves or the refrigerator, and in one case, three such surveys failed to detect the expired drug.
3. Respondent's violation is mitigated by its acceptance of responsibility and by its president's personal efforts to improve Respondent's compliance. Respondent now appears to understand the danger of delegating complete responsibility in this area to technicians without supervising their work.
4. Respondent has not demonstrated good cause for its failure to file a timely response to the Notice of Infraction. Consequently, no reduction in the \$500.00 penalty imposed by this administrative court's order of July 25, 2000 is appropriate. D.C. Code § 6-2704(a)(2)(A).

V. Order

Based on the foregoing findings of fact and conclusions of law, I will not suspend the proposed \$500.00 fine, but will reduce it in recognition of Respondent's acceptance of responsibility and its efforts to achieve compliance. Due to the lengthy period that the expired drugs remained available for sale, the reduction in the fine will be limited to \$100.00, making Respondent liable for a fine of \$400.00. The \$500.00 penalty for failing to respond to the Notice of Infraction will not be reduced.

Therefore, upon Respondent's answer and plea, its application for suspension of the fine, and the entire record in this case, it is hereby, this _____ day of _____, 2000:

ORDERED, that Respondent shall cause to be remitted a single payment totaling **NINE HUNDRED DOLLARS (\$900.00)** in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (fifteen (15) calendar days plus five (5) days for service by mail pursuant to D.C. Code § 6-2715). A failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of Respondent's license or permit pursuant to D.C. Code § 6-2713(f).

/s/ **10/13/00**

John P. Dean
Administrative Judge